

UPDATED: CDC Fall Vaccination Operational Planning Guide

Information on Bivalent COVID-19 Vaccines for Children Aged 6 Months Through 4 or 5 Years

BIVALENT COVID-19 VACCINE BACKGROUND INFORMATION

On June 28, 2022, independent experts on FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons. The advisory committee voted in favor of including a SARS-CoV-2 Omicron component in COVID-19 vaccines that would be used for boosters in the United States beginning in fall 2022. [FDA subsequently informed manufacturers seeking to update their COVID-19 vaccines that they should develop bivalent boosters](#) including a BA.4/5 valence specifically.

On August 31, 2022, [FDA amended the emergency use authorizations \(EUAs\)](#) of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine to authorize bivalent formulations of the mRNA vaccines for use as a single booster dose at least two months following the last primary series dose or booster. CDC's Advisory Committee on Immunization Practices (ACIP) met on September 1, 2022, and voted to recommend the use of bivalent vaccines as boosters. [CDC endorsed ACIP's recommendations](#) for the use of updated COVID-19 boosters from Pfizer-BioNTech for people aged 12 years and older and from Moderna for people aged 18 years and older. On October 12, 2022, FDA expanded the EUAs of bivalent COVID-19 vaccines to authorize their use as a single booster dose in younger age groups (bivalent Pfizer-BioNTech vaccine for children aged 5-11 years and bivalent Moderna COVID-19 vaccine for children aged 6-17 years). [CDC subsequently issued a recommendation](#) for the use of bivalent COVID-19 boosters among individuals aged 5 years and older.

At publication of this guide, bivalent mRNA COVID-19 vaccines are authorized and recommended as a single booster dose only in people who have completed a primary vaccination series. Currently, anyone aged 5 years or older who has completed at least a primary series is eligible for a bivalent mRNA booster, regardless of number or type of prior booster doses received so long as at least two months have passed since their last COVID-19 vaccine dose. In addition, monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for any age group.

Most COVID-19 vaccination providers are currently offering bivalent vaccines. Not all providers are expected to continue carrying primary series COVID-19 vaccines. While the potential exists for bivalent vaccines to become authorized for all primary series vaccination sometime in the future, until that point, jurisdictions will need to continue maintaining a safety net of monovalent COVID-19 vaccines for all age groups and give special consideration to groups with low rates of primary series completion, such as young pediatric age groups, or groups at highest risk of poor outcomes such as people who are severely immunocompromised and recommended to repeat the primary series. Providers planning to continue offering primary series COVID-19 vaccines will need to store both original (i.e., monovalent vaccine) and updated (i.e., bivalent vaccine) formulations.

BIVALENT COVID-19 VACCINES FOR NEW PEDIATRIC AGE GROUPS

If authorized by FDA, CDC anticipates a recommendation for bivalent COVID-19 vaccine for additional pediatric age groups in early to mid-December. Bivalent COVID-19 vaccine products expected to be under consideration in December include the bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and bivalent Moderna vaccine for children aged 6 months through 5 years.

At this time, it is expected that children in these age groups will be required to receive two doses of monovalent COVID-19 vaccine before receiving a dose of bivalent COVID-19 vaccine. Since Moderna's bivalent COVID-19

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vaccine is expected to be authorized as a booster, and Pfizer-BioNTech's is expected to be authorized as part of the pediatric primary series, mix-and-match use is NOT expected to be authorized.

It is expected that children aged 6 months through 4 years who received two doses of monovalent **Pfizer-BioNTech COVID-19 vaccine** will be authorized to receive a third dose of bivalent vaccine to complete their primary series. Children who received one dose of monovalent Pfizer-BioNTech COVID-19 vaccine would need to receive a second dose of monovalent Pfizer-BioNTech COVID-19 vaccine before receiving a dose of bivalent Pfizer-BioNTech COVID-19 vaccine. **It is expected that children aged 6 months through 4 years who received three doses of monovalent Pfizer-BioNTech COVID-19 vaccine to complete their primary series will not be authorized to receive a booster dose of bivalent COVID-19 vaccine at this time.**

It is expected that children aged 6 months through 5 years who received one dose of monovalent **Moderna COVID-19 vaccine** will need to receive a second dose of monovalent Moderna COVID-19 vaccine to complete their primary series before receiving a bivalent Moderna COVID-19 vaccine dose as a booster. (Children 5 years of age who completed the monovalent Moderna primary series are currently authorized to receive a bivalent Pfizer-BioNTech booster.)

Pfizer-BioNTech COVID-19 Vaccines

Expected characteristics of Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 6 months through 4 years:

- Ultra-cold freezer storage (-90°C to -60°C) until expiry
- NO FREEZER STORAGE (-25°C to -15°C)
- Refrigerate (2°C to 8°C) up to 10 weeks without puncturing
- Requires 2.2 mL diluent per vial (providers will NOT be able to opt out of receiving ancillary kits)
- Packaged in 10-dose vials in cartons of 10 vials each (100 doses total)
- Dose 3mcg/0.2mL
- Minimum order quantity of 100 doses
- Maroon cap identical to the monovalent Pfizer-BioNTech product for this age group
- New label identifying the product as a bivalent vaccine (i.e., Original and Omicron BA.4/BA.5)
- **Once punctured, each vial must be used within 12 hours**

Moderna COVID-19 Vaccines

Expected characteristics of Moderna bivalent COVID-19 vaccine for children aged 6 months through 5 years:

- NO ULTRA-COLD FREEZER STORAGE (-90°C to -60°C)
- Freezer storage (-50°C to -15°C) until expiry
- Refrigerate (2°C to 8°C) up to 30 days without puncturing
- Does not require diluent (providers will be able to opt out of receiving ancillary kits)
- Packaged in 2-dose vials in cartons of 10 vials each (20 doses total)
- Dose 10mcg/0.2mL
- Minimum order quantity of 100 doses
- Vial with dark pink cap and yellow border on the label
- **Once punctured, each vial must be used within 8 hours**

Ancillary Kits

Ancillary supplies will be provided, including a variety of 1-inch and 1.5-inch needles and syringes. An ancillary opt-out continues to be available for all non-diluent kits and would be available for Moderna bivalent COVID-19 vaccine for children aged 6 months through 5 years.

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- For Awardees, opt-out instructions can be found in the VTrckS library at: <https://vtrcks-library.cdc.gov/gm/folder-1.11.17315>
- For Federal Agencies/Commercial Partners, opt-out functionality is available in VPoP.

Pfizer-BioNTech bivalent COVID-19 vaccine for children aged 6 months through 4 years is expected to require diluent, so providers would NOT be able to opt out of receiving ancillary kits.

UPDATED LAUNCH PLAN FOR NEW PEDIATRIC AGE GROUPS

Doses of bivalent COVID-19 vaccines have been made available under thresholds rather than allocations. This means that at the start of each new order period, doses available for ordering are replenished up to the threshold for that order period (i.e., with each subsequent threshold, the full number of doses will be available to order).

Bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and bivalent Moderna vaccine for children 6 months through 5 years will each be a new product with a unique National Drug Code (NDC). Prior to a potential EUA, there will be a single pre-ordering period expected to begin at 10:00 a.m. ET on November 28, 2022, and to end on or about December 6, 2022, at 9:00 a.m. ET. Pre-ordering enables bivalent COVID-19 vaccines to be shipped immediately following EUA. Changes in this schedule are possible, so jurisdictions should continue to monitor instructions in case the order window is changed.

Pre-EUA Thresholds

- Doses of bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and bivalent Moderna vaccine for children aged 6 months through 5 years will be made available for jurisdictions, federal entities, and pharmacies to pre-order. Thresholds for jurisdictions will be determined on a pro rata basis (based on the eligible population rather than census population). **Threshold numbers will be posted in Tiberius for planning purposes before pre-ordering begins.**
- Pre-ordering of pediatric bivalent vaccine for these age groups is anticipated to start at 10:00 a.m. ET on Monday, November 28, 2022, and to end on or about Thursday, December 6, 2022, at 9:00 a.m. ET.
- Jurisdictions should begin to prioritize which sites would be first to receive doses based on various considerations (e.g., vaccinating those at highest risk for severe COVID-19 disease, such as children with certain medical conditions; ensuring vaccine equity; feasibility of sites efficiently implementing the vaccine program; operating hours conducive to receiving and administering initial shipments).
- Jurisdictions should pre-order sufficient vaccine to cover the initial anticipated demand.
- Doses that are pre-ordered will begin being processed for delivery following EUA. Expected delivery schedules will be dependent on the actual EUA date.
- Sites should plan to manage necessary freezer and refrigerator space when developing their overall fall vaccine plans.

There will be a **sufficient but finite supply** of pediatric bivalent COVID-19 vaccines for these age groups, which should be directed to providers with expected demand among eligible patients. Due to minimum order quantities, jurisdictions should consider internal distribution and hub-and-spoke operations to maximize ultra-cold freezer and refrigerator space and avoid wasting vaccine. Dashboards will be developed within Tiberius that will enable jurisdictions to view their order thresholds and optimally prioritize providers to receive initial shipments.

The public will be directed to [Vaccines.gov](https://www.vaccines.gov) to find providers offering pediatric bivalent COVID-19 vaccine for the younger age groups. After receiving their initial vaccine orders, providers should report their inventory to Vaccines.gov as soon as possible following receipt of vaccine. Providers are also strongly encouraged to report the minimum age (in months and years) for whom a location can administer vaccine.

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Post-EUA Thresholds

After the EUA is issued, ordering of bivalent pediatric vaccines for children in the younger age groups is expected to reopen against the remaining thresholds. Orders placed after EUA will be delivered following pre-orders and will arrive in sequence, noting initial launch may stretch the usual delivery windows. Additional information on new thresholds after the initial set of thresholds will be forthcoming.

The following summary table provides an estimated sequence of events based on bivalent pediatric vaccines for children in the youngest age groups receiving an EUA on or around December 8, 2022. Additional details regarding the vaccine ordering timeline and delivery of vaccine shipments will be updated when available.

Projected Timeline (All subject to change)	Action/Event	Comments
<i>Pre-EUA</i>		
11/22/22	Thresholds posted for planning (pro rata per jurisdiction)	Posted in Tiberius
11/28/22	Pre-ordering begins	10:00 a.m. ET opening
11/30/22	Special ad hoc all-awardee call with Pfizer-BioNTech and Moderna in attendance	
12/6/22	Pre-ordering ends	Cutoff at 9:00 a.m. ET
<i>Post-EUA</i>		
TBD (pending EUA)	CDC recommendation	
TBD (pending EUA)	First deliveries of pediatric bivalent vaccines arrive	
TBD (pending EUA, CDC recommendation)	Vaccine partner update calls	

UPDATED CONSIDERATIONS FOR NEW PEDIATRIC AGE GROUPS

To enhance readiness to launch the pediatric bivalent vaccine program for the younger age groups and begin administering vaccine, jurisdictions should identify providers who will receive the bivalent doses. Also, jurisdictions will need to balance making primary series vaccine accessible to those who would like to receive it while avoiding distributing inventories across too many sites and seeking to minimize vaccine loss.

Jurisdictions and providers are **strongly encouraged to adopt strategies to minimize unnecessary wastage**; however, **they should not miss any opportunities to vaccinate every eligible person** who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.

Pediatric bivalent COVID-19 vaccines will be made available to jurisdictions, pharmacies, and federal entities through pro rata thresholds (based on the eligible population rather than census population). Jurisdictions should create a distribution plan in coordination with local health departments and other partners and determine which sites will receive vaccine product, incorporating the considerations listed below.

Considerations for selecting sites to receive the initial pediatric doses include:

- Location and access to a range of populations (e.g., urban and rural, communities that may be disproportionately impacted by COVID-19) and ensuring that distribution to these groups is equitable to the extent possible.
- Ability to reach eligible [children at highest risk for severe COVID-19](#).
- Ability to handle 100-dose product configurations, depending on whether the jurisdiction has plans in place for redistribution.

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- Ability to administer both Pfizer-BioNTech and Moderna pediatric bivalent vaccines to meet anticipated community demand.
- Ability to efficiently vaccinate within 12 hours once a vial is opened (or within 8 hours for a vial of Moderna bivalent COVID-19 vaccine for children aged 6 months through 5 years). Sites should consider vial size and the expected demand when planning and scheduling individuals for vaccination, especially early in the program, to optimize supply.
- Ability to continue vaccinating children who already received primary series doses at a given location, given that mix-and-match use is not expected to be authorized.
- Ability to manage inventory to ensure availability of primary series doses, in addition to bivalent vaccine doses, in their local area when feasible.
- Overall readiness (e.g., staffing, training, scheduling capabilities).

Jurisdictions will be responsible for assuring primary vaccines remain available especially in populations where uptake of the primary series is lower. The vast majority of children aged 6 months through 5 years have not completed a primary series, so it is imperative that jurisdictions continue maintaining access to monovalent vaccines for this age group. It is anticipated that pediatric bivalent COVID-19 vaccines for the youngest age groups will be authorized as a single dose in children who have received two primary series doses, at a minimum interval after their second primary series dose.

It is expected that only homologous use of bivalent vaccines for children aged 6 months through 4 years will be authorized, meaning eligible children who received two doses of monovalent Pfizer-BioNTech vaccine would need to receive a bivalent Pfizer-BioNTech vaccine as their third dose. Similarly, eligible children who completed a primary series of Moderna vaccine would need to receive a bivalent Moderna vaccine as their booster.

Heterologous (mix-and-match) use is not expected to be authorized. (Children 5 years of age who completed the monovalent Moderna primary series are currently authorized to receive a bivalent Pfizer-BioNTech booster.)

It is expected that children aged 6 months through 4 years who received three doses of monovalent Pfizer-BioNTech COVID-19 vaccine to complete their primary series will not be authorized to receive a booster dose of bivalent COVID-19 vaccine at this time.

Public Readiness and Emergency Preparedness Act (PREP Act) Declaration:

The PREP Act and the PREP Act Declaration issued by the Secretary of the U.S. Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized or approved by FDA, including COVID-19 vaccines authorized for administration to children.

This authorization preempts state requirements that would otherwise prohibit, or effectively prohibit, these providers from administering the vaccine. The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements. For example, the Declaration authorizes pharmacists, pharmacy interns and pharmacy technicians nationwide to order and/or administer COVID-19 vaccines, influenza vaccines, and other vaccines authorized by FDA and recommended by CDC for children 3 years of age or older (please see: <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>).

VACCINE STORAGE MANAGEMENT TIPS

In order to continue offering primary series vaccines in addition to bivalent vaccines for use as boosters among people in various age groups who have completed their primary series, providers will need to keep multiple COVID-19 vaccine products in their inventory throughout the fall and winter. CDC recommends providers offer

simultaneous administration of all age-appropriate doses of vaccines for children, adolescents, and adults for whom no contraindications exist at the time of the healthcare visit.

As the demand for seasonal flu vaccines will also increase during this time, providers may have some concerns regarding vaccine storage space. To better maintain vaccine storage space, providers are encouraged to:

- Manage inventory to ensure availability of primary series doses, in addition to bivalent vaccines.
- Assess storage space to determine freezer and refrigerator capacity before placing orders for vaccine, taking into account anticipated flu vaccine inventory as appropriate.
- Check expiry dates on inventory and dispose of expired vaccine according to state and local regulations.
- Reduce vaccine ordering, reduce inventory, and place orders on an “as-needed” basis. In most instances, vaccine orders of existing COVID-19 vaccines can be delivered within 24-48 hours.
- Zero out old inventory in [Vaccines.gov](https://www.vaccines.gov), and ensure the publicly posted amount reflects actual inventory on hand. This will help to reduce confusion and assist the public in identifying a location where they can receive a vaccine.

READINESS CHECKLIST	
Main Theme	Key Activities for Readiness and Response
Supply and Ordering Readiness	<ul style="list-style-type: none"> <input type="checkbox"/> Determine which provider locations will receive initial supplies of each vaccine, balancing equitable access with vaccination capacity and consideration of initial demand. <input type="checkbox"/> Ensure that an expanded set of providers will be able to provide equitable and convenient access to all children <input type="checkbox"/> Finalize a list of providers and sequence of provider activation for the first week of vaccine deliveries. Jurisdictions will submit pre-orders for providers to facilitate delivery of orders. <input type="checkbox"/> Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available. <input type="checkbox"/> Optimize vaccine use by ordering supply to minimize unnecessary accumulation of inventory and wastage while also ensuring no vaccination opportunity is missed. <input type="checkbox"/> Plan for internal redistribution (e.g., in a jurisdiction) to reduce wastage & improve access. <input type="checkbox"/> Manage and accurately report on-hand product inventory to inform tracking near-expiry and redistribution.
Provider Readiness	<ul style="list-style-type: none"> <input type="checkbox"/> Ensure providers are enrolled to reach the key populations; identify providers who are not yet COVID-19 vaccination providers and facilitate their enrollment, especially providers who can fill a geographic gap in access and providers who care for people who are at increased risk for developing severe outcomes. <input type="checkbox"/> Identify VFC providers who are not yet COVID-19 vaccination providers and facilitate their enrollment, especially providers who can fill a geographic gap in access and providers who care for children from racial and ethnic minority groups or other communities that may be disproportionately impacted by COVID-19. This is especially important for children < 3 years, who generally will not be vaccinated in pharmacies but rather in primary care clinics. <input type="checkbox"/> Reach out to tribal nations within the respective areas for involvement in planning efforts. <input type="checkbox"/> Identify and facilitate enrollment of providers who frequently care for children with disabilities or special healthcare needs (e.g., children’s hospitals, pediatric subspecialty clinics). Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions, like anaphylaxis. <input type="checkbox"/> Encourage providers to offer COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., family members, community members). <input type="checkbox"/> Ensure providers are aware of resources to help support coadministration of COVID-19 vaccines and other vaccines, including influenza vaccines, during a visit.

Main Theme	Key Activities for Readiness and Response
	<ul style="list-style-type: none"> <input type="checkbox"/> Reinforce how providers are required to report certain adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and support providers in encouraging enrollment in v-safe. <input type="checkbox"/> Routinely evaluate the adequacy of the provider network, identifying gaps and whether additional vaccination locations (e.g., VFC providers, local public health departments, temporary vaccination clinics, FQHCs, rural health clinics) may be needed to further increase equitable access and ensure vaccine equity. <input type="checkbox"/> Encourage providers who are not able to offer COVID-19 vaccination to refer their patients to nearby vaccination providers.
IT Systems, Reporting and Monitoring	<ul style="list-style-type: none"> <input type="checkbox"/> Ensure electronic systems, including immunization information systems (IISs), are prepared to report and track vaccine administration. <input type="checkbox"/> Remember that the Special Project Provider label is required for COVID-19 vaccine ordering. Inclusion of this flag on the provider record indicates that the jurisdiction has signed the agreement with the provider to receive COVID-19 vaccines. <input type="checkbox"/> Leverage Tiberius dashboards to help plan for an appropriate network of pediatric providers that ensures access by all children. Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program.
Comms	<ul style="list-style-type: none"> <input type="checkbox"/> Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of unvaccinated key populations and populations recommended for bivalent vaccination. <input type="checkbox"/> Understand existing data, attitudes, and perceptions regarding COVID-19 vaccination (including co-administration with influenza vaccine) in terms of demand, provider types, and locations where vaccination would be preferred. Share these data with local jurisdictions and partners to help shape messages. <input type="checkbox"/> Develop communications products for providers, pharmacies, and the public that align with federal messaging and ensure materials are culturally and linguistically appropriate. <input type="checkbox"/> Leverage partnerships to help mobilize providers and promote COVID-19 bivalent vaccination messaging. <input type="checkbox"/> Engage and educate partners and trusted messengers (e.g., healthcare professionals, community leaders, faith leaders and faith-based organizations) as soon as possible. <input type="checkbox"/> Leverage partnerships (e.g., American Academy of Pediatrics [AAP] and American Academy of Family Physicians [AAFP] Chapters) to help mobilize providers and promote vaccination messaging to families.